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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,352	07/07/2003	Peter M. Bonutti	782-A03-003-1	7916
33771	7590	07/12/2010		
PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			07/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,352

Applicant(s)

BONUTTI, PETER M.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10-21, 24-26, 28, 30, 31, 33, 34 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-21, 24-26, 28, 30, 31, 33, 34 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 04/26/2010.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

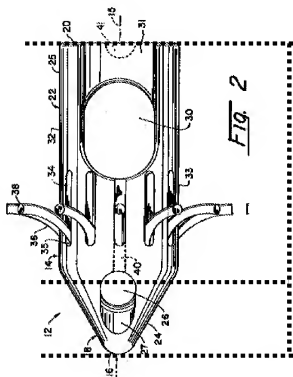
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 10-11, 18-20, 30, 32-35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by **Li** (U.S. Patent No. **5,505,735**).

Li discloses an anchor including a cylindrical body portion **22** being movable through an opening in the body tissue and defining a longitudinal central axis, said body portion having a maximum transverse length to the longitudinal central axis and said body portion having a first passage **30** extending through said body portion transverse to the longitudinal central axis for threading suture therethrough, a conical pointed end portion (part of **18**, seen in annotated Figure 2 below) for piercing the body tissue being connected to or extending from said body portion along said longitudinal central axis, said pointed end portion having a maximum transverse length transverse to the longitudinal central axis being no greater than the maximum transverse length of the body portion, both said body portion and said end portion having a second passage **26** formed parallel to said first passage which transversing said body portion and said end

portion for threading the suture therethrough. The pointed end portion may form an opening in body tissue when a force is applied to a trailing end of the body portion along the longitudinal central axis. The device may be made of a biodegradable material (col. 6, lines 11-15). A suture may be threaded through either passage (col. 6, lines 16-37).



Body portion

Pointed end portion

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-17, 21, 26, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**).

Li discloses the claimed device except for the body portion being made of allogenic, autogenic, xenogenic, cortical bone, or a single piece of freeze dried bone, or a material more rigid than bone to form an opening in bone. It would have been obvious to one of ordinary skill in the art to use any of the above materials with the device of Li to form an opening in bone, since the anchor of Li is used in bone and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, and to further anchor the device in bone tissue.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**) in view of **Schwartz** (U.S. Patent No. **6,306,159**) and **Hayhurst** (U.S. Patent No. **4,741,330**).

Li discloses the claimed device, as described above, except for a suture extending and being threaded through said first passage and second passage and being operative to rotate when under tension, and a retainer connected to the suture for

maintaining the tension in the suture which has a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture.

Schwartz teaches a suture **40** being passed through and extending through first **24** and second **26** passages and being threaded through said first passage and said second passage, wherein the suture is operative to rotate an anchor **20** when under tension, and a retainer connected to the suture for maintaining the tension in the suture (Figures 4-7; abstract, col. 2, lines 14-16). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Li with a suture going through first and second passages, as taught by Schwartz, in order to facilitate positioning of the anchor to close a tissue defect, thereby promoting healing (col. 4, lines 11-13).

Hayhurst teaches a retainer **68** having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture (see abstract, Figures 13-14, col. 8, lines 25-32). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a freely slidable retainer along the suture and being secured to the suture in order to maintain tension, as taught by Hayhurst, to Li in order to facilitate applying and maintaining tension to the suture to properly promote tissue healing (col. 3, lines 29-35).

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**), **Schwartz** (U.S. Patent No. **6,306,159**), and **Hayhurst** (U.S. Patent No. **4,741,330**), as applied to claim 24 above, and further in view of **Egan** (U.S. Patent No. **6,106,545**).

Li, Schwartz, and Hayhurst disclose the claimed device as discussed above, except for a retainer made of a material that becomes flowable when ultrasonic vibratory energy is applied.

Egan teaches a retainer **24** connected to a suture **22** that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place (col. 3, lines 5-30). It would have been obvious to one of ordinary skill to provide a retainer that becomes flowable when ultrasonic vibratory energy is applied, as taught by Egan, to Li, Schwartz, and Hayhurst since it was known in the art that retainers maintain tension in sutures and that retainers made of flowable material are beneficial in avoiding the challenging step of knotting the suture in place.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**), **Schwartz** (U.S. Patent No. **6,306,159**), and **Hayhurst** (U.S. Patent No. **4,741,330**) as applied to claim 24 above, and further in view of **Huxel** (U.S. Patent No. **6,503,259**).

Li, Schwartz, and Hayhurst disclose the claimed device as discussed above, except for a force distribution member being disposed between the retainer and the body tissue.

Huxel teaches a force distribution member **16** being disposed between a retainer and body tissue (Figure 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a force distribution member, as taught by Huxel, to Li, Schwartz, and Hayhurst in order to avoid over compression in one portion of tissue and to evenly distribute force on the surface of tissue (col. 4, lines 12-16).

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**) in view of **Whittaker** (U.S. Patent No. **5,417,712**).

Li discloses the claimed device except for a passage extending through said anchor at an acute angle to the longitudinal axis.

Whittaker teaches that a suture passage may extend at an acute angle to the longitudinal axis, such as in Figures 13 and 16. The passage ("central portion") extending at an angle may facilitate deformation of a suture **12** (col. 8, lines 28-30), and therefore it would have occurred to one of ordinary skill in the art to modify a passage of the anchor in Li for this purpose.

9. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Li (U.S. Patent No. **5,505,735**) in view of **Hayhurst** (U.S. Patent No. **4,741,330**).

Li discloses the claimed device except for a retainer slidable along a suture.

Hayhurst teaches a retainer **68** having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture (see abstract, Figures 13-14, col. 8, lines 25-32). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a freely slidable retainer along the suture and being secured to the suture in order to maintain tension, as taught by Hayhurst, to Li in order to facilitate applying and maintaining tension to the suture to properly promote tissue healing (col. 3, lines 29-35).

10. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Li** (U.S. Patent No. **5,505,735**) in view of **Hayhurst** (U.S. Patent No. **4,741,330**), as applied to claim 38 above, and further in view of **Egan** (U.S. Patent No. **6,106,545**).

Li and Hayhurst disclose the claimed device as discussed above, except for a retainer made of a material that becomes flowable when ultrasonic vibratory energy is applied.

Egan teaches a retainer **24** connected to a suture **22** that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place (col. 3, lines 5-30). It would have been obvious to one of ordinary skill to provide a retainer that becomes flowable when ultrasonic vibratory

energy is applied, as taught by Egan, to Li and Hayhurst since it was known in the art that retainers maintain tension in sutures and that retainers made of flowable material are beneficial in avoiding the challenging step of knotting the suture in place.

11. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (U.S. Patent No. **5,505,735**) in view of **Schwartz** (U.S. Patent No. **6,306,159**).

Li discloses the claimed device except for a suture being passed through first and second passages.

Schwartz teaches a suture **40** being passed through and extending through first **24** and second **26** passages and being threaded through said first passage and said second passage, wherein the suture is operative to rotate an anchor **20** when under tension, and a retainer connected to the suture for maintaining the tension in the suture (Figures 4-7; abstract, col. 2, lines 14-16). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Li with the suture going through first and second passages, as taught by Schwartz, in order to facilitate positioning of the anchor to close a tissue defect, thereby promoting healing (col. 4, lines 11-13).

Response to Arguments

12. Applicant's arguments filed 04/26/2010 have been fully considered but they are not persuasive.

13. Applicant argues that the passage **26** of Li is completely located within the pointed end portion **18** as seen in Figure 2, rather than formed in both of the body portion, where passage **30** is located, and the pointed end portion. However, the passage **26** may be considered to be part of the pointed end portion, as well as the body portion, since the pointed end portion may be designated as the distal part of **18** as shown in annotated Figure 2 above. Since no further definitions of the pointed end portion are recited to define over the designated pointed end portion and body portion, the device of Li reads on this limitation.

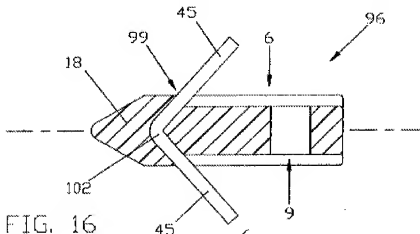
14. Applicant also argues that Schwartz teaches no retainer. However, the inner anchor **30** has a locking mechanism, which may be considered to be the retainer (see abstract, col. 5, lines 52-63), and therefore reads on this limitation.

15. In addition, applicant argues that Hayhurst's retainer is not "freely slidable" along a suture since it only allows uni-directional movement along the suture. However, the limitation "freely slidable" may pertain to uni-directional movement and not necessarily bi-directional movement, and therefore Hayhurst reads on the limitation.

16. In regards to applicant's argument that Huxel's force distribution member **16** not being disposed between a retainer and body tissue but rather between elements **12** and **14**, the examiner agrees that the gasket **16** is between elements **12** and **14**, but as seen

in Figure 8 the gasket is also between body tissue **02** and retainer **12**, and therefore reads on the claims.

17. Lastly, applicant argues that Whitaker the suture passages do not extend at acute angles to the longitudinal axis but rather are parallel to the axis in Figures 1 and 13. However, Figures 1 and 13 are not relied upon by the examiner, but rather Figures 13 and 16, (seen in Figure 16 below), and therefore Whitaker reads on the claims.



Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734